UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF PENNSYLVANIA

VINCENT W. FALA and JUDITH A. FALA	:	
	:	
Plaintiffs	:	**CIVIL ACTION NO. 3:19-1132**
	:	
v.	:	**(JUDGE MANNION)**
PENNSYLVANIA CVS PHARMACY, LLC	:	
	:	
Defendant	:	

MEMORANDUM

On July 2, 2019, plaintiffs Vincent and Judith Fala, ("Plaintiffs"), filed a complaint in this District, (Doc. 1), asserting various claims against defendant Pennsylvania CVS Pharmacy, LLC, ("Defendant"), for: professional negligence (Count I), corporate negligence (Count II), vicarious liability (Count III), and loss of spousal consortium (Count IV). After the commencement and progression of discovery, Plaintiffs filed a parallel action against Defendant asserting a claim for strict products liability pursuant to the Restatement (Second) of Torts, § 402A. As the two matters were identical except for the addition of the Plaintiffs' strict product liability claim, this Court, by Order, (Doc. 41), consolidated the two actions and adopted the amended complaint from the parallel action as the operative complaint in this matter, thus adding Plaintiffs' claim for strict product liability as Count V. (Doc. 45).

Pending before the Court is a motion to dismiss Plaintiffs' strict product liability claim raised in accordance with the Restatement (Second) of Torts, § 402A. (Docs. 42).[1] Viewing the evidence in a light most favorable to the non-moving party, the Court will **GRANT** the Defendant's motion to dismiss Count V of the amended complaint.

I. BACKGROUND

On October 4, 2018, plaintiff Vincent Fala, a resident of Dingman's Ferry, Pennsylvania, entered the CVS pharmacy located at 5122 Milford Road, East Stroudsburg, Pennsylvania, to receive a pneumococcal vaccine. This CVS pharmacy location was seemingly owned and operated by defendant Pennsylvania CVS Pharmacy, LLC, a limited liability company with a principal place of business at One CVS Drive, Woonsocket, Rhode Island. Upon arrival at the East Stroudsburg CVS, Vincent Fala was prescribed the Pneumovax 23 vaccine by Martin Duclose, M.D., and the vaccine was administered that same day to Mr. Fala's right arm "by an

[1] In its brief in support of its motion to dismiss, the Defendant initially states that "Plaintiffs' Amended Complaint should be dismissed in its entirety pursuant to Federal Rule of Civil Procedure 12(b)(6) based on existing Pennsylvania law which does not extend the rule of strict supplier liability to pharmacists." (Doc. 42 at 4). As the remainder of the Defendant's brief focuses solely on the Plaintiffs' strict liability claim and does not address the other four claims listed in the amended complaint, the Court will focus solely on the sufficiency of the Plaintiffs' Count V claim under the Restatement (Second) of Torts, §402A.

individual in a white coat believed to be a pharmacist working at the CVS whose name is Eric T. Wild."

On the evening of October 4, 2018, Plaintiffs allege that Mr. Fala "began having pain/discomfort in his right shoulder." Though Mr. Fala phoned the East Stroudsburg CVS and was told that the shoulder pain was normal, he returned to the CVS location on October 7, 2018, as he was experiencing "increased and significant pain and discomfort." The following day, Mr. Fala continued to experience pain and swelling in his shoulder, which led him to present himself at the Bryn Mawr Hospital where he was "found to have swelling in his right deltoid and his acromio-clavicular joint was tender-to-palpation." Upon further examination in the Emergency Department at Bryn Mawr Hospital, Mr. Fala allegedly was found to have a fluid collection around his right shoulder, "slight erythematous color of upper arm to clavicle," and an "elevated sedimentation rate and c-reactive protein rate."

On October 8, 2018, Mr. Fala was taken into the operating room at Bryn Mawr Hospital for an "incision and drainage of superficial and deep abscess," and he was diagnosed with suffering from "right shoulder septic arthritis" with "pus collections and a 'massive rotator cuff tear.'" Mr. Fala remained hospitalized until October 13, 2018. During a follow-up examination after his release from care, Mr. Fala had cultures taken that indicated "[t]he other possible diagnosis is pseudoseptic arthritis of the shoulder, which has been reported following pneumococcal vaccination." As

a result, Plaintiffs contend that "Defendant's agent(s) and/or employee(s) and/or workmen and/or servant(s) directly and proximately caused Mr. Fala's right shoulder injury by administering the Pneumovax 23 vaccine in an improper location."

II. STANDARD

The Defendant's motion to dismiss is brought pursuant to the Federal Rule of Civil Procedure Rule 12(b)(6). This rule provides for the dismissal of a complaint, in whole or in part, if the plaintiff fails to state a claim upon which relief can be granted. Fed. R. Civ. P. 12(b)(6). The moving party bears the burden of showing that no claim has been stated, Hedges v. United States, 404 F.3d 744, 750 (3d Cir. 2005), and dismissal is appropriate only if, accepting all of the facts alleged in the complaint as true, the plaintiff has failed to plead "enough facts to state a claim to relief that is plausible on its face," Bell Atl. Corp. v. Twombly, 550 U.S. 544, 570 (2007) (abrogating "no set of facts" language found in Conley v. Gibson, 355 U.S. 41, 45-46 (1957)). The facts alleged must be sufficient to "raise a right to relief above the speculative level." Twombly, 550 U.S. at 555. This requirement "calls for enough fact[s] to raise a reasonable expectation that discovery will reveal evidence" of necessary elements of the plaintiff's cause of action. Id. at 556. Furthermore, in order to satisfy federal pleading requirements, the plaintiff must "provide the grounds of his entitlement to relief," which "requires more than labels and conclusions, and a formulaic recitation of the elements of a

cause of action will not do." Phillips v. County of Allegheny, 515 F.3d 224, 231 (3d Cir. 2008) (brackets and quotations marks omitted) (quoting Twombly, 550 U.S. at 555).

In considering a motion to dismiss, the court generally relies on the complaint, attached exhibits, and matters of public record. Sands v. McCormick, 502 F.3d 263 (3d Cir. 2007). The court may also consider "undisputedly authentic document[s] that a defendant attaches as an exhibit to a motion to dismiss if the plaintiff's claims are based on the [attached] documents." Pension Benefit Guar. Corp. v. White Consol. Indus., Inc., 998 F.2d 1192, 1196 (3d Cir. 1993). Moreover, "documents whose contents are alleged in the complaint and whose authenticity no party questions, but which are not physically attached to the pleading, may be considered." Pryor v. Nat'l Collegiate Athletic Ass'n, 288 F.3d 548, 560 (3d Cir. 2002). The court, however, may not rely on other parts of the record in determining a motion to dismiss. *See* Jordan v. Fox, Rothschild, O'Brien & Frankel, 20 F.3d 1250, 1261 (3d Cir. 1994).

III. DISCUSSION

Defendant argues that the Plaintiffs fail to provide "sufficient factual allegations" to support their Count V claim for strict products liability pursuant to the Restatement (Second) of Torts, § 402A. In addition, Defendant contends that Pennsylvania law does not extend strict supplier liability to

pharmacists, which would further foreclose Plaintiffs' claims under Section 402A. The Court will address these two arguments in turn.[2]

A. Strict Liability for a Product Supplier

Plaintiffs' amended complaint alleges that "[a]s a result of the unreasonably dangerous and defective condition of the *vaccine injectable*, which CVS sold in the stream of commerce to Plaintiff, the defendant is strictly liable to the Plaintiff pursuant to §402A of the Restatement (Second) of Torts." (Doc. 40 at ¶ 50) (emphasis added). In accordance with this claim, the Plaintiffs contend that the Defendant is liable for "(a) failing to properly and adequately design the vaccine injectable; (b) failing to properly and adequately manufacture the injectable; (c) failing to warn the Plaintiff of the dangerous nature of the vaccine injectable; and (d) such other defects as shall be revealed in the course of discovery." (Id.).

Thus, "Plaintiffs are not alleging that some defect in the vaccine itself is what caused Mr. Fala injuries," but that the Defendant is "strictly liable for

[2] The parties both substantially refer in their briefing to exhibits and the testimony of defendant CVS's employee, Mr. Wild, which was given as part of discovery. Generally, "a district court ruling on a motion to dismiss may not consider matters extraneous to the pleadings." In re Burlington Coat Factory, 114 F.3d 1410, 1426 (3d Cir. 1997) (citing Angelastro v. Prudential-Bache Sec. Inc., 764 F.2d 939, 944 (3d Cir. 1983)). Though courts may consider any "document integral to or explicitly relied upon in the complaint … without converting the motion [to dismiss] into one for summary judgment," this ability does not expand to documents outside the pleadings. Id. (citation omitted).

the vaccine 'injectable.'" (Doc. 45 at 12 (citing Doc. 40 at ¶ 49)). Such claims, however, are separate and apart from the Plaintiffs' main assertions throughout their amended complaint, which focus on the "negligent administration" of the vaccine allegedly delivered in an improper location on Mr. Fala's right arm. As a result, the analysis regarding Plaintiffs' Section 402A claims must be centered around the provision of the "vaccine injectable" by the Defendant.[3]

The doctrine of strict products liability has been developed over time to protect consumers from the dangers inherent in a modern capitalist society, and in Webb v. Zern, 220 A.2d 853 (Pa. 1966), Section 402A of the Restatement (Second) of Torts was adopted as the law of strict products liability in Pennsylvania. Section 402A, providing such consumer protections, states in part:

> (1) One who sells any product in a defective condition unreasonably dangerous to the user or consumer or to his property is subject to liability for physical harm thereby caused to the ultimate user or consumer, or to his property, if
>
> (a) the seller is engaged in the business of selling such a product, and

[3] Plaintiffs do not provide a clear definition or description of a "vaccine injectable," which is not a term of art that this Court recognizes. The Court must instead assume that Plaintiffs refer to the medical device used to inject the vaccine into a patient's arm. Though such an assumption may typically make a clear decision regarding a plaintiff's strict products liability claim difficult, the Court, in light of the overall legal findings set forth below, is able to conduct a sufficient analysis.

(b) it is expected to and does reach the user or consumer without substantial change in the condition in which it is sold.

(2) The rule stated in Subsection (1) applies although

(a) the seller has exercised all possible care in the preparation and sale of his product, and

(b) the user or consumer has not bought the product from or entered into any contractual relation with the seller.

Restatement (Second) of Torts, § 402A. Noticeably, at the heart of a Section 402A claim resides a requirement that the defendant has sold a product that is defective. *See* Francioni v. Gibsonia Truck Corp., 372 A.2d 736, 739 (Pa. 1977) ("[e]ngagement in the business of 'selling' (leasing) products is, of course, a basic requirement of the rule").

Plaintiffs argue that defendant CVS provided both a product and a service through the provision and administration of the Merck Pneumovax 23 vaccine. Accepting this argument as true, however, it cannot also reasonably be said that a "vaccine injectable," which Plaintiffs argue was the defective product, was either sold to Mr. Fala or was provided as a service. Instead, a "vaccine injectable," which the Court must assume is the device used to administer the vaccine, would merely reflect a tool used by Defendant's employee to provide a service and not a product that was purchased by or provided to Mr. Fala.

The Defendant cites various cases that provide analysis regarding Section 402A claims.[4] Specifically, Cafazzo v. Cent. Med. Health Servs., Inc., 668 A.2d 521, 524 (Pa. 1995) states that Pennsylvania courts have made clear that the "provision of medical services is regarded as qualitatively different from the sale of products, and, rather than being an exception to 402A, is unaffected by it." Id. (citing Hector v. Cedars-Sinai Medical Center, Inc., 180 Cal.App.3d 493 (1986)). In this regard, this Court, as in Cafazzo, must "distinguish medical services from merchandising," as medical service providers in Defendant's position cannot be considered "sellers, providers, suppliers or distributors of products such as to activate 402A" for every instrument utilized in a medical procedure. Id. at 525. As such, the "vaccine injectable" utilized by the Defendant to provide Mr. Fala with the Merck Pneumovax 23 vaccine can only be seen as "a product incidental to the provision of medical services" and not a product falling under the purview of strict liability under the Restatement (Second) of Torts, § 402A. Id. at 523.

[4] The Defendant also refers to Comment k of Section 402A in their initial brief, which states that "[t]here are some products which, in the present state of human knowledge, are quite incapable of being made safe for their ordinary and intended use. These are especially common in the field of drugs…." *See* (Doc. 42 at 9 (citing Coyle v. Richardson-Merrell, Inc., 584 A.2d 1382, 1385 (Pa. 1991)). As the Plaintiffs' strict product liability claims do not focus on the vaccine provided to Mr. Fala, Comment k is not applicable to this analysis.

B. Strict Liability for a Defective Product

Throughout the entirety of their amended complaint, the Plaintiffs, in regard to their Section 402A claim, solely allege that the Defendant is liable for "(a) failing to properly and adequately design the vaccine injectable; (b) failing to properly and adequately manufacture the injectable; (c) failing to warn the Plaintiff of the dangerous nature of the vaccine injectable; and (d) such other defects as shall be revealed in the course of discovery."

Nevertheless, even if the "vaccine injectable" in question was to be considered a product provided by the Defendant to the Plaintiffs, *but see supra* Section III(A), the Plaintiffs have failed to sufficiently allege that such a product was defective. In fact, though the Plaintiffs broadly argue that the Defendant failed to properly and adequately design, manufacture, or warn of the dangers associated with the vaccine injectable, nowhere in their amended complaint do the Plaintiffs state what defect they believe the vaccine injectable possessed. They also do not allege that the Defendant was tasked with the designing of, manufacturing of, or warnings associated with such instruments in the first place. Instead, almost the entirety of the Plaintiffs' amended complaint focuses on the apparent improper administration of the vaccination shot Mr. Fala received at the East Stroudsburg CVS on October 4, 2018, while any assertions of a defect to the "vaccine injectable" can only be described as conclusory allegations that fail

to state a claim upon which relief can be granted.[5] *See* Twombly, 550 U.S. at 555 (facts alleged must be sufficient to "raise a right to relief above the speculative level."). Therefore, Count V of the Plaintiffs' amended complaint for strict products liability claim under Restatement (Second) of Torts, § 402A will be dismissed.[6]

IV. CONCLUSION

For the reasons discussed above, the Court will **GRANT** the Defendant's motions to dismiss Plaintiffs' strict product liability claim (Count V) pled in accordance with Restatement (Second) of Torts, § 402A and will not provide the Plaintiffs leave to amend. Defendant's additional request that

[5] As the parties have already undertaken discovery, the Plaintiffs' inability to provide any reference to what defect they seemingly argue was affecting the "vaccine injectable" further undermines any argument that additional discovery will provide any added clarity to such a claim.

[6] Courts may grant leave to amend a complaint before dismissing it as merely deficient. *See, e.g.*, Fletcher-Harlee Corp. v. Pote Concrete Contractors, Inc., 482 F.3d 247, 252 (3d Cir. 2007); Grayson v. Mayview State Hosp., 293 F.3d 103, 108 (3d Cir. 2002); Shane v. Fauver, 213 F.3d 113, 116-17 (3d Cir. 2000). "Dismissal without leave to amend is justified only on the grounds of bad faith, undue delay, prejudice, or futility." Alston v. Parker, 363 F.3d 229, 236 (3d Cir. 2004). For Count V of the amended complaint, however, further amendment would be futile as the Plaintiffs have failed to show that they may still sufficiently allege that the "vaccine injectable" should be considered a product or service under Restatement (Second) of Torts, § 402A or that additional discovery would allow Plaintiffs the ability to uncover evidentiary support for their claim.

the "Amended Complaint should be dismissed in its entirety" will be **DENIED**.

A separate order will follow.

s/ *Malachy E. Mannion*
MALACHY E. MANNION
United States District Judge

Date: September 30, 2021
19-1132-01